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| APPLICATION NO. | FILING DATE                | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |  |
|-----------------|----------------------------|----------------------|-------------------------|------------------|--|--|
| 09/437,912      | 11/09/1999                 | KEITH R. MCCRAE      | 6056-257                | 8628             |  |  |
| 23973           | 7590 03/25/2003            | •                    |                         |                  |  |  |
| DRINKER I       | BIDDLE & REATH             | EXAMINER             |                         |                  |  |  |
| ONE LOGAN       | N SQUARE<br>CHERRY STREETS |                      | ROBINSON                | SON, HOPE A      |  |  |
|                 | HIA, PA 19103-6996         |                      | I ADDITION I            | DARCO MILADED    |  |  |
|                 |                            |                      | ART UNIT                | PAPER NUMBER     |  |  |
| e .             | •                          |                      | 1653                    | ۸                |  |  |
|                 | •                          |                      | DATE MAILED: 03/25/2003 | ا کہ             |  |  |
|                 |                            |                      |                         | $\sim$           |  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

3.4%

Application No. 09/437,912

Applicant(s)

McCrae

Examiner

**HOPE ROBINSON** 

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| The MAILING DATE of this communication appears on the cover sheet with the correspondence address  |  |  |                    |  |  |  |
|--|--|--|--------------------|--|--|--|
|  | for Reply  |  |                    |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.   |  |  |                    |  |  |  |
| - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  |  |  |                    |  |  |  |
| - If NO p<br>- Failure<br>- Any re   | period for reply specified above is less than thirty (30) days, a reply within the<br>period for reply is specified above, the maximum statutory period will apply a<br>to reply within the set or extended period for reply will, by statute, cause the<br>ply received by the Office later than three months after the mailing date of the<br>patent term adjustment. See 37 CFR 1.704(b). | ind will expire SIX (6) I<br>ne application to becom | MONTHS from ABANDO | om the mailing date of this communication.<br>NED (35 U.S.C. § 133). |  |  |
| Status   |  |  |                    |  |  |  |
| 1) 💢   | Responsive to communication(s) filed on <u>Jul 5, 200</u>  | 02   |                    | <u> </u>   |  |  |
| 2a) 🗌  | This action is <b>FINAL</b> . 2b)   ✓ This act   | ion is non-final.                                    |                    |  |  |  |
| 3) 🗆   | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.   |  |                    |  |  |  |
| Disposi  | tion of Claims   |  |                    |  |  |  |
| 4) 💢   | Claim(s) 1-4, 8, 9, 16, 19, 22, and 30-49  |  |                    | is/are pending in the application.                                   |  |  |
| 4  | a) Of the above, claim(s)  |  | . 7                | is/are withdrawn from consideration.                                 |  |  |
| 5) 💢   | Claim(s) 16, 19, 22, and 36-49   |  |                    | is/are allowed.  |  |  |
| 6) 💢   | Claim(s) 1-4, 8, 9, 30-32, 34, and 35  |  |                    | is/are rejected.   |  |  |
| 7) 💢   | Claim(s) <u>33</u>   |  |                    | is/are objected to.  |  |  |
| 8) 🗆   | Claims   | are  | subject            | to restriction and/or election requirement.                          |  |  |
| Applica  | tion Papers  |  |                    |  |  |  |
| 9) 🗌   | The specification is objected to by the Examiner.  |  |                    |  |  |  |
| 10)  | The drawing(s) filed on is/are a) $\square$ accepted or b) $\square$ objected to by the Examiner.  |  |                    |  |  |  |
|  | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |                    |  |  |  |
| 11)  | The proposed drawing correction filed on   | is:  | a)□ a              | pproved b) $\square$ disapproved by the Examiner.                    |  |  |
|  | If approved, corrected drawings are required in reply t  | to this Office act                                   | ion.               |  |  |  |
| 12)  | The oath or declaration is objected to by the Exami  | ner.   |                    |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |  |  |                    |  |  |  |
| 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |  |  |                    |  |  |  |
| a) □ All b) □ Some* c) □ None of:  |  |  |                    |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |  |                    |  |  |  |
|  | 2. Certified copies of the priority documents have been received in Application No   |  |                    |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  *See the attached detailed Office action for a list of the certified copies not received. |  |  |                    |  |  |  |
| _  |  |  |                    |  |  |  |
| <ul> <li>14) ★ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</li> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> </ul>  |  |  |                    |  |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |  |  |                    |  |  |  |
| Attachment(s)  |  |  |                    |  |  |  |
|  | tice of References Cited (PTO-892)   | 4) Interview Sun                                     | nmary (PTO         | -413) Paper No(s)  |  |  |
|  | tice of Draftsperson's Patent Drawing Review (PTO-948)   |  |                    | Application (PTO-152)  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)  |  |  |                    |  |  |  |

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### **DETAILED ACTION**

- Applicant's response to the Office Action mailed August 9, 2002 in Paper No. 16 on July
   2002 is acknowledged.
- 2. Claims 2 and 16 have been amended. Claims 1-4, 8-9, 16, 19, 22, 30-49 are pending.
- 3. The following grounds of rejection are or remain applicable:

## Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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1.

4. Claims 1-4, 8-9 and 30-32 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ferreira et al. (WO 97/05258, February 13, 1997) based on a formula wherein X is any amino acid,  $X_1$  is a fragment thereof containing at least one amino acid and  $X_2$  is zero amino acids.

5. Claims 1 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by (FARH) HOECHST JAPAN, Accession Number AAR75186, JP07082172-A, 1995, based on a formula wherein X is any amino acid,  $X_1$  is a fragment thereof containing at least one amino acid and  $X_2$  is zero amino acids.

The reference teach a sequence that encompasses the basic sequence "Gly-His-Lys-X-Lys". In addition, the reference teaches a compound that is a 100% identical to the compound as set forth in SEQ ID NO: 9 of the instant application. Although the reference sequence is longer the claims are anticipated because the claims recite the open language "having" "comprising". Thus, the limitations of the claims are met by the reference.

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6. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by (SUMU) SUMITOMO SEIYAKU KK, Accession Number AAW07625, JP08208692-A, 1996.

The reference teaches a compound that is a 100% identical to the compound as set forth in SEQ ID NO: 8 of the instant application. Although the reference sequence is longer the claim is anticipated because the claim recites the open language "having". Thus, the limitations of the claim are met by the reference.

#### Art of Record

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(FARH) HOECHST JAPAN, Accession Number AAR75186, JP07082172-A, 1995, teach the sequence set forth in SEQ ID NOS: 5 and 7 which are recited in the method claims (see for example claim 16). Although the abstract does not explicitly state that the reference teach a method of inhibition of angiogenesis, it is disclosed that the sequence corresponds to a human kiningen that is useful in wound healing.

8. Applicant's arguments filed December 9, 2002 were not sufficient to over come the rejection of record under 35 U.S.C. 102. Regarding the rejection under 35 U.S.C. 102, applicant

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contends that claim 1 recites the minimum sequence of Gly-His-Lys-X-Lys because X<sub>1</sub> must always contain at least one amino acid "Gly" and as the Ferreria reference teaches Pro it does not anticipate the claimed invention. This contention is not accurate as page 9 of the specification indicates that "N-terminal truncation fragment" means a fragment obtained from a parent sequence by removing one or more amino acids from the N-terminus thereof, thus, the "or more amino acids" of the definition could result in only one amino acid remaining in the N-terminus and the claim does not specify what amino acid residue the one has to be. Applicant's comments on pages 4-6 of the response have been considered, however, the tables presented are not a part of the specification. Note that Table 1 on page 26 is not the same as Table 1 depicted in the response. In addition, the plain language of the claim which is also emphasized by applicant on page 4 is the "N-terminal truncation fragment thereof containing at least one amino acid". The claim does not recite "N-terminal truncation fragment thereof containing at least one amino acid which is glycine". Thus applicant's statements that a Gly remains is not persuasive thus the art of record (Ferreira) anticipates the claims. It is suggested that the claims are amended to remove the alternative language and limit the formula/compound with the phrase "consisting of" as the comprising language is open. Note also that the newly cited reference reads on the claimed formula and teaches the basic "Gly-His-Lys-X-Lys" as emphasized by applicant. Note also that new grounds of rejection have been instituted under 35 U.S.C. 102(b).

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#### Conclusion

9. Claims 16, 19, 22 and 36-49 are free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

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Hope Robinson, MS

Patent Examiner

Christopher Id how

CHRISTOPHER S. F. LOW SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600